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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on September 14, 2006 is acknowledged. Claims 1-6, 8-10, and 12-16 are pending and under consideration. Claims 1, 6, and 12 have been amended. Claims 13-16 have been newly added. Claims 1-6, 8-10, and 12-16 are under examination.

Rejections Withdrawn

1. In view of Applicants' amendment, the rejection of claims 1-6 and 8-10 under 35 U.S.C. 102(e) as being anticipated by Brin et al (U.S. 2005/0260231 A1) in light of Wikipedia (On line Encyclopedia) is withdrawn.

2. In view of Applicants' amendment, the rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Gassner et al (U.S. Patent 6,447,787 B1) is withdrawn.

Rejections Maintained

3. Claims 1-5, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf) for the reasons set forth in the previous Office action in the rejection of claims 1, 5, and 12.

Applicant argues that:

1) Kwon does not disclose or suggest the use of a reconstituted liquid solution of botulinum toxin to treat a skin disorder

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a reconstituted liquid solution of botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions, thereby treating the skin disorder. Subsequent claim 12 is drawn to a method for treating a skin disorder to a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of dermatofibroma, keloid, mole, granuloma and keratose, thereby treating the skin disorder.

With regard to Point 1, there is no material difference between that which has been claimed and that of the prior art. Moreover, Kwon discloses the use of Botox toxin, which as evidenced by Allergan, necessarily has been reconstituted because Botox is shipped as a sterile, vacuum-dried purified botulinum toxin type A (see page 1; Description). Consequently, Kwon has met the limitations of claims 1-5, and 12.

Additionally, Kwon discloses a method of administering a safe and effective amount of botox toxin (Botulinum Toxin Type A) for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses (page 6, paragraph 0077). Moreover, Kwon discloses administering the botulinum toxin via a patch (topical). As Kwon administers the same composition as that which has been

claimed to treat the same conditions (i.e. lesions, corns, warts, calluses, and bunions). Kwon necessarily would administer the same amount of botulinum toxin in order to be effective (i.e. between 1 unit and about 3,000 units). The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin.

New Grounds of Rejection Necessitated by Amendment

35 USC § 112, New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has added new claim 13, which recite in part "the step of administering a therapeutically effective amount of a reconstituted liquid solution of botulinum toxin via syringe to a location of a skin disorder of the patient...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Applicant does not point to

support for the claims as amended. What is supported by the specification is "to reconstitute vacuum-dried BOTOX™, sterile normal saline without a preservative is used by drawing up the proper amount of diluent in the appropriate size syringe" (see page 11, lines 23-25). However, the specification does not disclose anything regarding administering a therapeutically effective amount of a reconstituted liquid solution of botulinum toxin via syringe to a location of a skin disorder of the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon (U.S. 2004/0087893 A1).

Claim 6 and 8-10 are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of locally administering between 1 unit and 3000 units of a reconstituted liquid solution of botulinum toxin to a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions, thereby treating the skin disorder.

Kwon teaches a method of administering a safe and effective amount of botox toxin (Botulinum Toxin Type A) for treating lesions or abnormal skin features, such as

pimples, corns, warts, calluses, bunions and keratoses (page 6, paragraph 0077). Kwon teaches administering the botulinum toxin via a patch (topical). Kwon administers the same composition as that which has been claimed to treat lesions, corns, warts, calluses, and bunions. Kwon necessarily administers the botulinum toxin in an amount of between 1 unit and about 3,000 units. Moreover, the examiner asserts that there is no material difference between that which has been claimed and that of the prior art. Kwon teaches the use of Botox toxin, which as evidenced by Allergan, necessarily has been reconstituted because Botox is shipped as a sterile, vacuum-dried purified botulinum toxin type A (see Allergan, Description, pages 1-4, http://www.allergan.com/download/BotoxPI.pdf).

Kwon differs from the instantly claimed invention in that Kwon does not specifically teach the local administration of botulinum toxin.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to administer the botulinum toxin locally in order to reduce the amount of botox needed to be therapeutically effective. One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for treating a skin disorder.

With regard to claims 8-10, due to the mode of action of botox its administration would necessarily reduce a pain/inflammation associated with as well as reduce the size of a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
3/14/07

ROBERT A. ZEMAN
PRIMARY EXAMINER